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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Patent Office Board of Appeals

APPLICANT: Philip Connolly

G.A.U: 3678

SERIAL NO.: 10/045,803

EXAMINER: K. Hendricks

FILED: January 12, 2002

St. Louis, Missouri

FOR: Method of Enhancing Absorption and
Utilization of Protein

Date: August 4, 2004

D.N.: 7287

Hon. Commissioner of Patents & Trademarks
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**BRIEF FOR APPLICANT
RESUBMITTED**

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Citation of Cases and Statutes

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Cases:

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I. Real Parties In Interest

The parties in interest in this particular application include the inventor, Philip Connolly, and the Company to which he has assigned this application, Commercial Proteins Corporation.

II. Related Appeals and Interferences

There are no related appeals, or interference proceedings, pertaining to the subject matter of this patent application.

III. Status of Claims

The examiner issued a final rejection on October 7, 2003. Applicant filed an Amendment B, after final rejection, on or about October 30, 2003. On December 2, 2003, the examiner issued an office action stating that the Amendment B failed to place the application into condition for allowance. Thus, at that time, for purposes of appeal, the claims in the case were 1, 2, 3, 7, 8, and 10.

Applicant has previously filed a Notice of Appeal on February 5, 2004. At this time, it appears that the claims in this application include Claims 1, 2, 3, 7, 8, and 10. These are the claims upon which the Appeal Brief is filed.

IV. Status of Amendments

All of applicant's amendments subsequent to the final rejection apparently have been entered by the examiner, and therefore, the claims upon appeal are 1, 2, 3, 7, 8, and 10, as set forth in the Amendment B. These claims are set forth in the Appendix.

More specifically, applicant filed an Amendment A on July 16, 2003. That Amendment was rejected, for enablement, informalities, and obviousness on references to Meister et al. Applicant submitted the Amendment B on October 30, 2003 overcoming the informalities and attempting to render the claims more definite and non-obvious, but the examiner continued his rejections.

The Notice of Appeal was filed, and the brief was submitted accordingly.

V. Summary of the Invention

This invention uses a milk protein concentrate, or any of the other related proteins, which are fortified or cultured with a probiotic bacteria or combination of several probiotic bacteria. The milk protein concentrate which has been fortified with beneficial organisms to improve the overall digestive health of the consumer while providing the basic building blocks for muscle tissue, such as amino acids. The invention can be used to enhance absorption of protein from the gastrointestinal tract and utilization of proteins in a high protein diet. The net effect from consuming such a cultured protein seeks improved health, a higher daily degree of anabolism over catabolism, and a larger net gain in lean body tissue. In the sports nutrition area, the serious athlete or body builder should see better results in gaining muscles and will feel better in the long run. Most consumers will see increased strength, muscle development, resistance to disease.

The invention also relates to the production of a milk protein concentrate, and an improved method for manufacturing the same. The invention provides for the oral administration of a milk protein concentrate, i.e., the milk protein of skim milk that has been concentrated to a higher percentage of protein by removal of undesired constituents, such as lactose, ash, and fat. The protein concentrates are combined with probiotic bacteria including *bifido* bacterium, *acidophilus*, and yogurt culture bacteria. These bacteria are considered to be the most important intestinal bacteria for humans, and are thus classified as probiotic, which benefit living organisms.

The invention is also a method of production and administration of an improved performance milk protein concentrate that maximizes the efficient production of protein that can grow healthy muscle tissue. The invention utilizes a high quality milk protein concentrate and adds probiotic bacteria to it. The invention makes protein absorption more efficient when metabolized by the body.

VI. Issues

The issue concerned is whether or not Claims 1, 2, 7, and 10 are anticipated under §102(b), or in the alternative, rendered obvious under §103(a), over the patent to Bohren.

A second issue is whether Claim 1 remains rejected under §102 as anticipated, or in the alternative obvious, over any of the patents to Kronberg, Jameson, Nielsen, or Kosikowski.

A third issue is whether Claims 1-3, 7-8, and 10 are rejected under §103 as obvious over Meister.

Finally, the further issue is whether Claims 1, 7, and 10 are unpatentable over Meister '609, in view of Kronberg, and further in view of Bohren under 35 U.S.C. § 103(a).

VII. Grouping of Claims

There appears to be three groups of claims in this appeal, one group is Claims 1, 2, and 3.

The second group is claims 7 and 8.

The third group is claim 10.

Applicant bases its appeal upon three groups of claims. These include the group as set forth above. It is applicant's position that all the claims do not stand or fall together. To the contrary, it is believed that claims 1, 2, and 3, constitute one group, claims 7 and 8 are a second group, and claim 10 is a third group. Within the groups, the claims may stand or fall together, but not all of the claims collectively.

Claims 1, 2, and 3, comprising a first group of claims, will stand or fall together.

Obviously, claims 7 and 8 are a second group, and will stand or fall together.

The third group of claims, claim 10, stands or falls alone.

VII. Argument

Claims 1, 2, 3, 7, 8, and 10:

Issue 1

The examiner rejected Claims 1, 2, 3, 7, 8, and 10, under 35 U.S.C. § 112 2nd paragraph and applicant attempted to amend independent Claims 1, 7, and 10 in order to clarify the 112 problems. The amendment B was filed after final and then the examiner stated that the amendment met the second new rejection expressed in the October 7, 2003 Office Action but failed to comply with the first new rejection expressed in same. Hence, it is believed that the claims finally rejected, of this first group, would be independent Claims 1, 7, and 10 and dependent Claims 2, 3, and 8.

Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion of more protein than regularly consumed. Consuming a concentrate of milk protein and probiotic bacteria, a human augments their protein eaten with meals. Claims 1, 7, 10 specify a range of total protein consumed daily including regular protein from meals and the present invention. The range as claimed provides one skilled in the art a range of total protein consumed so that the practitioner adjusts each individual's protein consumption to fall within the claimed range.

A practitioner, such as a physician, dietician, and the like, interviews an individual about their diet and meals. With diet information and food value tables, a practitioner determines the individual's starting daily protein intake. The practitioner then subtracts the starting daily protein intake from the claimed range to provide a range of actual concentrate to administer. The range of actual concentrate permits the practitioner to adjust concentrate consumption to meet the needs of the individual and still fall within the claimed range of total daily protein consumption. The training of a practitioner provides the skill in the art to interview individuals regarding diet and meals and to compute initial protein consumption using food value tables.

Issue 2

Claims 1, 7, and 10 define a method of enhancing protein absorption by humans during digestion. The enhancement arises from a concentrate of milk protein and probiotic bacteria. In one embodiment, the present invention filters liquid skim milk to a high concentration of protein and then adds probiotic bacteria to the concentrated liquid. The inoculated liquid is then spray dried. In an alternate embodiment, the present invention has a high protein milk powder mixed with a powder containing the probiotic bacteria. The inoculated concentrated powder is then mixed until homogeneous. In both embodiments, a human consumes the present invention in liquid form reaping the benefits from more efficient protein digestion encouraged by the probiotic bacteria. Two part protein concentrates appear in the '465 patent. Bohren describes a two part acidic milk powder having an acid compound coated in an edible fat with an emulsifier. This is distinct from two parts combined in a concentrate independent of their acidity or coating characteristics. Claims 1, 7, and 10 clearly describe a milk concentrate with a range of protein content and a range of probiotic bacteria concentration. To the contrary, Bohren '465 emphasizes pH and acid coating in its claimed structure.

Issue 3

Claims 1, 7, and 10 define a two part milk concentrate having a range of protein and a range of probiotic bacteria in either liquid or powder form. The range of protein makes up the major part and the probiotic bacteria make up the minor part of the concentrate. The concentrate provides protein for delivery to a human and probiotic bacteria to accelerate that delivery. A milk powder having a major part and a minor part appears in Kronberg '524. The minor part is treated by bacteria to convert sugar in skim milk thus, acidifying the minor part. The major part remains the same or has sugar added. Combined and dried, the major part and the minor part resist clumping in storage and then other bacteria upon reconstitution with water. This is distinct from powdered bacteria added to protein in a concentrate to aid absorption of protein by a human upon

reconstitution in water. Claims 1, 7, and 10 describe with clarity a two part concentrate of bacteria and protein but do not claim bacteria that inverts sugar into an acidic solution.

Issue 4

Claims 1, 7, and 10 establish either a liquid or powder concentrate of milk having ranges of protein and probiotic bacteria ingredients. For the liquid concentrate form, filtered skim milk has probiotic bacteria added. The bacteria laden skim milk is then spray dried under gentle low heat into powder form. For the powder concentrate form, powdered milk has powdered probiotic bacteria added. The two powders are then mixed mechanically to distribute the bacteria homogeneously in the concentrate. A spray dried milk powder arises in Meister '609. Meister claims a spray of food and a spray of bacteria combined and subsequently dried in at least a 100 deg C environment with mixing air to drop the temperature so some of the bacteria survive. This is distinct from powdered bacteria added to liquid or powdered milk and then spray dried or mechanically mixed respectively in a moderate temperature environment. Claims 1, 7, and 10 clearly describe combining protein and probiotic bacteria prior to drying or mixing.

It is believed that the particular method of enhancing absorption and utilization of protein of this invention, as now claimed herein, is not so suggested by the prior art, whether it be individually viewed, or in combination. While the examiner states that Meister '609 co-sprays two components to form a combined powder, it is submitted that Meister shows nothing more than two liquids, one containing bacteria, sprayed into a chamber and air dried at high temperature, no better than what is shown previously in Bohren and Kronberg, and therefore, suggests nothing with respect to a desired total daily protein consumption utilizing bacteria. Bohren simply discloses an acidic compound coated in fat solid at room temperature and Kronberg merely reveals a two part milk powder with one part being acidic and both frankly, are not believed to suggest anything in

the way Meister could be modified, to come up with the applicant's claimed invention. If suggestion is not provided by the prior art, then perhaps obviousness may also not be so apparent, in view of the case of In re Geiger, 815 F.2d 686 (Fed. Cir. 1987).

More specifically, with respect to the rejection by the examiner of claims 1-2, 7 and 10, under §102(b), as anticipated by, or, in the alternative, under §103(a), as obvious over Bohren, the following comments can be made.

Claim 1 defines a method of promoting protein absorption and utilization from the gastro intestinal track of a subject, such as in athletes or body builders, and comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria. Claim 2 defines the group from which the probiotic bacteria are selected. Claim 7 defines the further method of promoting protein utilization, wherein the probiotic bacteria is selected from the group consisting of the bifido bacteria, etc. And, composition is administered in an amount of the combination sufficient to increase the subject's total daily consumption of protein to between about 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day. Claim 10 defines the method of promoting higher ratio of anabolism as compared to catabolism, for promoting muscle tissue growth, and promoting amino acid production in the intestinal track of the athlete for promoting the utilization of protein consumed by the athlete. And, probiotic bacteria used is selected from the group consisting of bifido bacteria, etc., a specific daily consumption intake.

Bohren may disclose the preparation of *Lactobacillus bulgaricus* and *streptococcus thermophilus*, within his powder formed composition, it is submitted that the does not equate the usage of this type of bacteria at the specific consumption levels, at a specific gram weight per kilogram of body weight per day. Furthermore, it is submitted that Bohren does not define the amount of organisms within the range per gram of milk protein concentrate, as suggested in claim 1. Hence, it is questioned as to whether the method of claim 1, and as set forth in its dependant claim 2, in addition to the method of claims 7 and 10 are anticipated in the manner as suggested by the examiner under §102.

In addition, the Bohren patent does not appear to define or suggest the usage of its acidified milk product in a powder form for promoting protein absorption and utilization from the gastro intestinal track of a subject, namely, the athlete, or body builder, in the specified amounts as set forth in these claims. And, since he does not suggest towards the usage of a milk protein concentrate, supplemented by the identified bacteria, in these amounts, it is argued that Applicant's claimed method, likewise, is not rendered so obvious from this particular prior art patent.

With respect to the rejection of claim 1, under §102(b), as anticipated by, or, in the alternative, under §103(a) as obvious over Kronberg, Jameson, et al, Nielsen, or Kosikowski, et al, the following comments can be made.

What claim 1 defines has already been reviewed previously. It is submitted that none of the four references cited as a basis for anticipation, suggest Applicant's claimed method. And in particular, none of the references teach or suggest that it would be desirable to provide a subject with a sufficient amount of the claimed combination of milk protein concentrates, and probiotic bacteria, to increase the subject's total daily consumption of protein to between approximately 1.5 grams and 4.0 grams of protein per kilogram of body weight per day. This does not appear to be addressed or suggested in any of these four prior art.

The examiner also has rejected claims 1-3, 7-8, and 10 under §103, as being obvious over Meister, et al. Meister is primarily concerned with the process for obtaining and utilizing a dehydrated food composition that yet contains a probiotic lactic acid bacteria, rather than any method for usage of this type of composition or its absorption within an athlete on a high protein diet. Meister goes into detail in describing the method to carry out his process, where the culture of one or more species of probiotic lactic acid bacteria is prepared. No doubt Meister refers to a number of bacteria in the detailed description of his invention, but the essence of his invention, and what is suggested by it, is how to develop a culture of lactic acid bacteria that preferably contains at least 10^7 live cell colonies per gram, where apparently the composition is spray dried, in order

to reduce its water content, of up to seventy percent (70%) by weight, to attain the dehydrated product. This is not the subject of Applicant's invention in the first instance. As previously reviewed, Applicant provides a method of promoting protein utilization and absorption in the athlete, who is on a high protein diet, thru an oral administration of a combination of the milk protein concentrate, and the probiotic bacteria, where administered amount of the combination is sufficient to increase the subject's total daily consumption protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day. This prior art patent to Meister does not suggest this type of method or invention.

With respect to these three additional rejections, Applicant refers once again to the case of In re Geiger, supra, and in addition, with respect to anticipation, the Board has recently held that anticipation is not established if it is necessary to pick, choose, and combine various portions of a disclosure, not directly related to each other by teachings or reference, in order to find that the application claim reads on that reference. See the case of Ex parte Beuther 71 USPQ 1313 (BdPat&Int2004). In other words, where the prior art is directed towards different usages of ingredients, or different methods, such as for drying a probiotic composition, that is not the same as providing for a specific mixture of a probiotic composition, with a milk protein concentrate, and then administering that composition in a very specified amount based upon the kilogram of body weight of the athlete, per day.

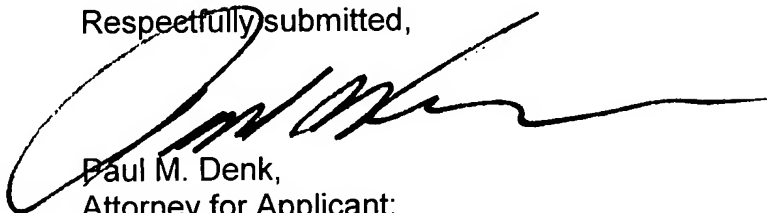
VIII. Conclusion

It is submitted that patentable subject matter is set forth in the remaining claims of this application. It is believed that the claim subject matter enables one skilled in the art to determine definitively a range of protein amount administered. It is believed that the claimed subject matter is just not rendered so obvious, to one of ordinary skilled in the art, nor is it even suggested by any combination of the prior art as cited by the examiner, notwithstanding the examiner's position. Hence, it is believed that patentable subject matter is set forth in the claims remaining in this application.

The Board's review of this matter would be appreciated.

If any additional charges are due, please debit our deposit account #040731.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul M. Denk', written over the typed name.

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Appendix

1. A method of promoting protein absorption and utilization from the gastrointestinal tract of a subject comprising the oral administration of a combination of milk protein concentrates and probiotic bacteria in an amount sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day; the milk protein concentrate having a protein content of about 65% to about 90% and there being about 100,000 to about 50,000,000 probiotic bacteria organisms per gram of milk protein concentrate.

2. The method of claim 1 wherein the probiotic bacteria is selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*,, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof.

3. The method of claim 1 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus* and *Streptococcus thermophilus*.

7. A method of promoting protein utilization and absorption in a subject on a high protein diet comprising the oral administration of combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the subject being administered an amount of the combination sufficient to increase the subject's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.

8. The method of claim 7 wherein the probiotic bacteria consists of *Bifidobacterium longum* combined with *Lactobacillus bulgaricus*, *Streptococcus thermophilus*, or combinations thereof.

10. A method of promoting higher ratio of anabolism as compared to catabolism, promoting muscle tissue growth, promoting amino acid production in

the intestinal tract in an athlete and promoting the utilization of protein consumed by the athlete, the method comprising the consumption by the athlete of a combination of milk protein concentrates and probiotic bacteria, the probiotic bacteria being selected from the group consisting of *bifido* bacteria, *Lactobacillus plantarum*, *Lactobacillus helveticus*, *Lactobacillus paracasei*, *Lactobacillus bulgaricus*, *Streptococcus thermophilus* and combinations thereof; the athlete consuming an amount of the combination sufficient to increase the athlete's total daily consumption of protein to between approximately 1.5 grams and approximately 4.0 grams of protein per kilogram of body weight per day.